MAIL STOP RCE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	R. Wooley et al.	Attorney Docket No.: UGRF123796
Application No.:	09/955,657	Art Unit: 1615 / Confirmation No.: 1163
Filed:	September 18, 2001	Examiner: M.P. Young
Title:	MEDICAL COMPOSITIONS, DRESSINGS AND METHODS FOR TREATING MICROBIAL INFECTIONS OF SKIN LESIONS	

RESPONSE TO FINAL OFFICE ACTION

Seattle, Washington 98101

September 1, 2005

TO THE COMMISSIONER FOR PATENTS:

In view of the remarks that follow, applicants respectfully submit that all of the pending claims are in condition for allowance. Reconsideration and favorable action are requested.

Rejection of Claims 1, 2, 5-15, 18-22, and 56-62 Under 35 U.S.C.§103(a) as Being Unpatentable Over the Combined Disclosures of Raad et al. (U.S. Patent No. 5,688,516, Hereafter the "'516 patent," and U.S. Patent No. 6,165,484, Hereafter the "'484 patent") and Kruse et al. (U.S. Patent No. 5,646,151, Hereafter the "'151 patent")

The '484 Patent: As a preliminary matter, applicants note that, in the Office Action mailed 07/01/2005, the examiner does not explain how the teachings of the '484 patent contribute to the rejection of Claims 1, 2, 5-15, 18-22, and 56-62 under 35 U.S.C.§103(a).

The '516 Patent: The Examiner characterizes the '516 patent as disclosing a method of treating Gram positive and negative bacterial infections by applying a composition of chelating agents such as EDTA and triethylene tetramine dihydrochloride and various anti-bacterial agents, including oxytetracycline. (Col. 4, lines 31-53; Col. 5, lines 37-53.) Applicants note that the claims of the present application recite the use of an anti-bacterial composition that includes a pharmaceutically acceptable anti-bacterial agent, a pharmaceutically acceptable chelating agent, TRIS, and a pharmaceutically acceptable carrier. Applicants note that the '516 patent does not

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teach or suggest the desirability of including TRIS with the chelating agent and anti-bacterial agent disclosed in the '516 patent.

Moreover, the claims of the present application recite that the chelating agent and the anti-bacterial agent have concentrations selected to allow synergistic cooperation between the anti-bacterial agent and chelating agent to inhibit proliferation of the bacterial population of a skin injury or a surface lesion of a human or an animal patient (see, e.g., Claim 1). Applicants submit that there is no teaching or suggestion in the '516 patent regarding the desirability of selecting concentrations of the chelating agent and anti-bacterial agent to allow synergistic cooperation between them.

Additionally, the compositions disclosed in the '516 patent are characterized as being a mixture of particular "non-glycopeptide antibiotics and selected chelating and antithrombotic agents" that fulfill the objectives listed in the "Background of the Invention" section of the '516 patent ('516 patent, Col. 4, lines 24-27). The objectives listed in the "Background of the Invention" are as follows:

> It is an object of the invention to provide a composition having both an anti-staphylococcal and antifungal (anti-Candida) activity effective against free-floating and adherent organisms embedded in biofilm as well as having activity against other microorganisms that may cause foreign body infections. It is a further object of the invention to provide an anticoagulant agent and/or method that would prevent and alter/dissolve a polysaccharide-rich fibrous glycocalyx biofilm layer. Such a pharmaceutical agent would optimally provide an anticoagulant that would prevent thrombotic occlusion of the catheter lumen as well as thrombin formation. Additional objects of the invention include providing an agent that could be given intraluminally without a toxicity concern to humans and to provide methods that would kill adherent staphylococci and Candida. Such methods would preferably not include the use of the same or similar agents that a clinician would use therapeutically (such as Vancomycin, Ampho B, or Azoles). ('516 patent, Col. 4, lines 7-24.)

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Thus, the invention disclosed in the '516 patent is primarily directed to the treatment of microbial films that develop on implanted catheters, and other implanted medical devices. To the best of applicants' knowledge and belief, it is not an objective of the '516 patent to provide compositions useful for inhibiting proliferation of a bacterial population on a skin injury or surface lesion of a human or animal patient, as recited in the claims and specification of the present application. Indeed, to the best of applicants' knowledge and belief, there is no teaching in the '516 patent that the compositions disclosed in the '516 patent are effective at inhibiting proliferation of a bacterial population on a skin injury or surface lesion of a human or animal patient.

The '151 Patent: The Examiner characterizes the '151 patent as disclosing topical formulations comprising chelating agents such as EDTA and antibiotic agents such as neomycin, amikacin and tetracyclines. (Col. 33, lines 3-38; Col. 34, lines 25-48; Col. 41, line 59-Col. 43, line 54.) The Examiner states that the reference establishes the knowledge in the art of combining chelating agents and antibiotic/fungal agents in order to treat skin injuries topically. The Examiner argues that a skilled artisan would be motivated to include the chelating agents and antibiotics of the '516 patent into the formulation of the '151 patent in order to treat a wider range of bacterial infections.Applicants note that the claims of the present application recite the use of an anti-bacterial composition that includes a pharmaceutically acceptable anti-bacterial agent, a pharmaceutically acceptable chelating agent, TRIS, and a pharmaceutically acceptable carrier. To the best of applicants' knowledge and belief, the '151 patent does not teach or suggest the desirability of including TRIS in the compositions disclosed in the '151 patent.Moreover, the claims of the present application recite that the chelating agent and the anti-bacterial agent have concentrations selected to allow synergistic cooperation between the anti-bacterial agent and chelating agent to inhibit proliferation of the bacterial population of a skin injury or a surface

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lesion of a human or an animal patient (see, e.g., Claim 1). Again, there is no teaching or suggestion in the '151 patent regarding the desirability of selecting concentrations of the chelating agent and anti-bacterial agent to allow synergistic cooperation between them.

The Examiner further argues that:

> one of ordinary skill in the art would have been motivated to follow the teachings of the '151 reference by treating infections with topical formulation comprising chelators. It would be well within the level of skill in the art to substitute and/or combine the any number of active ingredients in the formulation of '151, which teaches topical systemic treatment of infections, with the active components taught by '516, particularly with formulation comprising chelating agents. (Office Action mailed July 01, 2005, page 3, paragraph 5.)

Applicants respectfully disagree with the Examiner's assertion that the '151 patent "teaches topical systemic treatment of infections." The '151 patent teaches "compounds having kappa opioid agonist activity, compositions containing them, and method of using them as analgesics." ('151 patent, Col. 2, lines 18-20.) As explained in the "Background of the Invention" section of the 151 patent,

> Compounds which are κ-receptor agonists act as analgesics through interaction with κ opioid receptors. The advantage of these agonists over the classical μ receptor agonists, such as morphine, lies in their ability to cause analgesia while being devoid of morphine-like behavioral effects and addiction liability. ('151 patent, Col. 1, lines 42-47.)

Thus, the '151 patent teaches compounds that have useful analgesic properties. The '151 patent is not directed to the treatment of microbial infections. Consequently, applicants submit that one of ordinary skill in the art would not be motivated to combine the active ingredients in the formulation of '151 with the active components taught by '516.

For the foregoing reasons, applicants submit that the combination of the '516, '151 and '484 patents does not teach or suggest the subject matter of Claims 1, 2, 5-15, 18-22, and 56-62 of the present application.

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